

Appl. No. : 10/807,643  
Filed : March 23, 2004

### REMARKS

This Amendment is in response to the Office Action mailed November 10, 2004 in the above captioned application.

In the Office Action, Claims 1 through 7 and 9 through 22 were rejected over the prior art as discussed below. Claim 8 was objected to, as allowable if rewritten into independent form.

In this Amendment, Claim 19 has been cancelled and new Claims 23 through 42 have been added. Claims 20 through 22 have been amended. Claims 1 through 18 and 20 through 42 thus stand pending following entry of the foregoing amendments.

In the Office Action, the Examiner objected to the specification as lacking a definition of the term "Os". Paragraph [0011] of the specification has been revised as provided herein, to clarify that the term Os is used as synonymous with ostium. No new matter has been added by this amendment, and the Applicants believe that this amendment should favorably resolve the Examiner's objection.

The drawings stand objected under 37 C.F.R. § 1.83(a), as failing to show Figure 10. Paragraph [0027] has been amended herein, to correct what is believed to have been a typographical error. No new matter has been added.

Claims 1 through 2, 5 through 7 and 9 through 17 stand rejected under 35 U.S.C. § 102(b), as anticipated by U.S. Patent No. 6,096,071 to Yadav. In order for a rejection under § 102(b) to be sustained, every element in the claim, in the same relationship as in the claim, must be disclosed in a single prior art reference. If even a single limitation in the claim is missing from the prior art reference, the rejection under § 102 is improper and should be removed.

In the present case, each of the independent claims contains at least one limitation that is not disclosed in Yadav. As a consequence, the § 102(b) rejections in view of Yadav do not appear to be proper, and should be withdrawn.

In particular, Yadav fails to disclose at least the following limitation of Claim 1:

Said anchors adapted to extend axially into and expandably circumscribe at least one half of the main vessel wall when the scaffold is implanted in the branch lumen with said one end adjacent the Os.

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To the contrary, Yadav discloses a stent having four short flanges 12 to facilitate accurate positioning of the stent at an ostium of a branch vessel. Describing Figures 5 and 6, reproduced below, Yadav recites the following (column 4 lines 32 through 34):

With reference to FIGS. 5 and 6, stent 10 is depicted with the flange 12 fully extended after withdrawal of sheath 20, and is inserted firmly and securely with vessel 18.

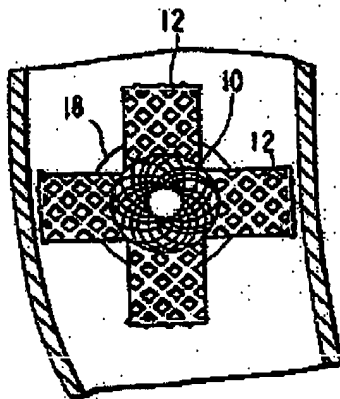
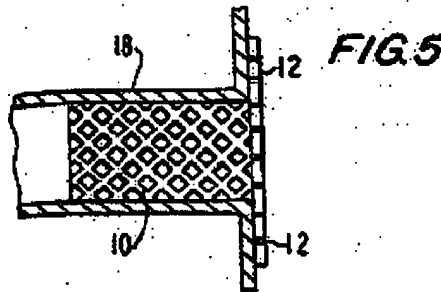


FIG. 6

As seen in FIGS. 5 and 6, the flange 12 is long enough to facilitate positioning and retaining the stent at the ostium, but sufficiently short that it is essentially planar as deployed and extends well less than one half of the main vessel wall circumference. This is consistent with the Yadav

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specification which, for example, recites the problem to be solved as follows (column 1 lines 15 through 19):

The tubular stents currently available are very difficult to position in the ostium of arteries; since the sent is either inserted too far leaving a critical portion of lesion uncovered, or the stent protrudes into the aorta.

The short flange 12 illustrated in Figures 5 and 6 is all that is needed to achieve the desired solution. Facilitating accurate placement of the stent at the ostium is an important objective of the Yadav invention (column 1 lines 45 through 49):

Lastly, it is an object of the present invention to provide for a novel stent which comprises flanges to permit the accurate positioning of the stent, while at the same time preventing dislodgement of the stent from the position where it had been placed.

The objective of facilitating placement and anchoring of the stent is achieved by the relatively short flanges disclosed by Yadav.

In addition, Yadav describes the flanges as positioned in the ostium, with no reference to extension beyond the ostium and into the main vessel. (See, for example, column 2 lines 34 through 37):

The flaring members are deformed so that they substantially conform to the ostium of the tubular organ, thereby firmly securing the ostial stent at that site.

Without admitting any clinical efficacy to the Yadav device, it appears from a mechanical standpoint that the anchoring and locating objectives are fully met by the short flanges as illustrated in Yadav. No reason is provided for departing from the implanted configurations illustrated in Figures 5 and 6, and, instead, extending flanges to a significantly greater length such that they circumscribe at least one half of the main vessel wall. Doing so would impose a requirement for additional procedures not disclosed in Yadav, to insure that the extensions into the main vessel lie

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flat against the wall, such as a follow up (undisclosed) touch up balloon dilatation procedure or other step apparently unnecessary in an execution of the type contemplated by Yadav.

Thus, Applicants respectfully submit that Yadav fails to disclose every element of Claim 1, and as a consequence, the rejection of Claim 1 is not believed to be properly sustainable over Yadav. Dependent Claims 2 through 10 are therefore necessarily novel over Yadav, and Applicants respectfully request the removal of the rejections of Claims 1 through 7 and 9 through 10 under 35 U.S.C. § 102 over Yadav.

Independent Claim 11 recites at least the following method step which is nowhere disclosed in Yadav:

And circumferentially deforming the anchors to circumscribe at least a portion of the main vessel wall and open a passage through the anchors.

As described above, Yadav discloses the use of relatively short flanges 12 which surround the opening to the branch vessel, for the purpose of positioning and anchoring the branch vessel stent. As illustrated, for example, in Figure 5, the length of the flanges 12 are taught to be sufficiently short relative to the curvature of the main vessel such that they lie relatively flat against the vessel wall. Follow up procedures for conforming the disclosed flanges against the main vessel wall to circumscribe at least a portion of the main vessel wall and open a passage therethrough are unnecessary. Indeed, no such circumferentially deforming step is disclosed or suggested in Yadav.

In contrast, Applicants submit that Claim 11 involves the positioning of a prosthesis having axially extending anchors which depend for a sufficient distance into the main vessel that a follow on balloon dilatation procedure or other procedure is desirable to conform the anchors to at least a portion of the main vessel wall, as is described in detail in Applicants' specification.

In view of the foregoing, Applicants respectfully submit that Yadav fails to disclose at least one element of Claim 11, and, as a consequence, the rejection of Claim 11 and dependent Claims 12 through 22 should be withdrawn.

Applicants note with appreciation the Examiner's indication of the allowability of dependent Claim 8, if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Claim 8 as filed depended directly from independent Claim 1, and new independent Claim 23 corresponds to the combination of original Claim 1 and Claim 8.

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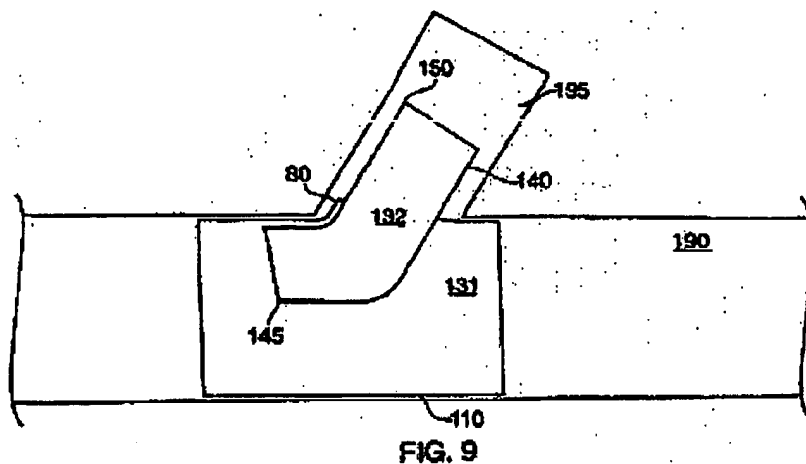
New dependent Claims 24 through 31 correspond to original dependent Claims 2 through 7 and 9 through 10. Accordingly, Applicants respectfully submit that new Claims 23 through 31 are in condition for allowance.

New Claim 32 corresponds to a combination of original Claim 11 and 19. New dependent Claims 33 through 42 correspond to original dependent 12 through 18 and 20 through 22.

Original Claim 19 stands rejected under 35 U.S.C. § 103(a) as unpatentable over Yadav in view of Richter. According to the Examiner, Richter teaches that a second stent can be deployed within the first stent. The Examiner asserts that it would therefore have been obvious to one having ordinary skill in the art at the time the invention was made to take the invention of Yadav and deploy a second prosthesis through the passageway and anchors.

As noted by the Examiner, Yadav fails to disclose the deployment of a second prosthesis within the passage through the anchors. However, Applicants respectfully submit that Richter fails to disclose or suggest a modification to the Yadav procedure in a manner that would produce Applicants' claimed invention, and respectfully request allowance of new Claim 32 which amounts to the removal of the §103 rejection with respect to Claim 19.

Richter is directed to a two-part modular bifurcation stent system, in which a main vessel stent is provided with a side opening. The main vessel stent is deployed in the main vessel, with the side opening aligned with the branch lumen. A second, branch stent is thereafter expanded across the branch aperture, such that a proximal end 145 of the branch stent is positioned within the main vessel stent and a distal end 150 of the branch stent is positioned within the branch vessel. See, for example, Figure 9 in the Richter patent:



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Richter is therefore directed to a profoundly different stent system than Applicants' present claimed invention. For example, Richter fails to disclose the positioning of a prosthesis such that a scaffold lies within a branch vessel and at least two circumferential anchors extend into the main vessel. Richter additionally fails to disclose circumferentially deforming any anchors to circumscribe at least a portion of the main vessel wall, and Richter fails to disclose the step of deploying a second prosthesis within the passage through the anchors.

To the contrary, Richter discloses implantation of the main vessel stent first, and advancement of the branch vessel stent from the inside out through a side wall aperture in the main vessel. Nothing in Richter would motivate a person of ordinary skill in the art to expand the length of the Yadav flanges and to circumferentially deform the flanges to circumscribe at least a portion of the main vessel wall and to deploy a second prosthesis within the passage formed in the main vessel by the step of circumferentially deforming the flanges to circumscribe at least a portion of the main vessel wall.

Not only does the art of record fail to provide a motivation to one of skill in the art to combine the teaching of Yadav and Richter, it is apparent that even if such a combination of technologies were achieved, it would fail to disclose or suggest Applicants' present claim invention.

As a consequence, Applicants respectfully submit that new Claim 32 is neither disclosed nor suggested by the combination of Yadav and Richter, and an indication of allowability of new independent Claim 32 and dependent Claims 33 through 42 is respectfully requested.

The cancellation of Claim 19 created an antecedent basis irregularity for Claims 20 through 22, which has been resolved by the amendments to Claims 20 through 22.

### **CONCLUSION**

In view of the foregoing, Applicants respectfully submit that all pending claims of the present application are in condition for allowance, and such action is earnestly solicited. If, however, any questions remain, the Examiner is cordially invited to contact the undersigned so that any such matter may be promptly resolved.

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Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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